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EXAMINER

GORDON, BRIAN R

ART UNIT PAPER NUMBER

1743

DATE MAILED: 05/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/486,531

Applicant(s)

HUSAR ET AL.

Examiner

Brian R. Gordon

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 February 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 96-138 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 96,98,100-115,122,125,126,128-130 and 132-138 is/are rejected.
- 7) ☒ Claim(s) 97,99,116-121,123,124,127 and 131 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 13.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Priority

1. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed in parent Application No. PCT/EP98/05146, filed on August 13, 1998.

Specification

1. The substitute specification filed February 19, 2003 has been accepted.
2. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

3. The disclosure is objected to because of the following informalities:

On page 30 (of substitute specification) reference numeral 14a designates both an "inlet valve" and a "non-return valve".

Appropriate correction is required.

Response to Arguments

2. Applicant's arguments with respect to claims 1-95 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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5. Claims 96, 98, 100-101, 103-115, 122, 126, 128-129, 132, and 136-137 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear if the "joint printed circuit board" is being claimed as an element of the invention. It is suggested that the claim be amended to read "wherein at least two selected from the group comprising the proportioning controls,"

As to claim 98, it is unclear if the "an actuator module" is being claimed as an element of the invention.

As to claim 100, it is suggested that the claim be amended to read "wherein the reservoir is provided with at least one selected from the group comprising [of] cooling means..."

As to claim 100, it is suggested that the claim be amended to read "wherein the reservoir is provided with at least one selected from the group comprising [of] cooling means..."

As to claim 101, it is unclear what is the "means" of the last paragraph. It appears as if the claim should read "a heating means provided at least in one selected from the group comprising [of] the micro-diaphragm"

Claims 103 and 105-112, 115, 126, 128 appear to be a method claims in which the operation of the device is given in a certain condition. It is suggested that claims be amended to recite that the device is capable or adapted to perform the functions or operations to clearly establish the structural limitations of the device.

In claim 104, the word "filing" should be "filling".

Claim 112 is unclear and it is suggest that the claim be rewritten to clearly claim applicant's intent. For example "....proportioning control means adapted to control a volume of liquid being proportioned by controlling a stroke volume or stroke volumes of the micro-diaphragm pump during aspiration or dispensing of the liquid."

As to claim 113, it is suggested that the claim be amended to read: "wherein at least two selected from the group comprising the micro-diaphragm pump..."

As to claim 114, it is unclear if the micro-diaphragm pump and open-jet proportioner are both considered as elements of the invention for in the second paragraph it appears as if only one of the two are required however in the following paragraphs references are made to both as to indicate both are including in the device which would contradict the at least one clause of the second paragraph. It is suggested that the claim be amended to read: "with at least one selected from the group comprising the micro-diaphragm..."

As to claim 122, it is suggested that the claim be amended to read "wherein at least one selected from the group comprising [of] the..."

As to claim 125, it is unclear how the liquid column is affected, for the claim implies that liquid is expelled from the reservoir in operation in one direction, but does not clear recite what happens in the operation of the second direction. Is the liquid sucked into the reservoir?

It is suggest that claim 129 be amended to "wherein at least two selected from the group comprising [of] the micro-diaphragm,"

As to claim 132, it is unclear what is meant by "nozzle shape". It is unclear what applicant considers to be nozzle shaped for there is no standard to determine what is considered as such.

Claims 136-137 should be amended to recite: "selected from a group comprising".

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 102-115, 125-126, 129-130, and 132-138 are rejected under 35 U.S.C. 102(b) as being anticipated by van Lintel, US 5,224,843.

van Lintel discloses a micropump system. Pumping takes place within the micropump as a result of the deformation of a plate (12) using a piezo-electric pad (13) (actuator module). The deformation produces a variation in volume within a pumping chamber (15) defined inside a plate (11) which is made of a material which can be machined using photolithographic processes.

An object of the invention to provide a micropump having a first wafer of a material capable of being machined using photolithographic technology in such a way as to define with at least one second support wafer bonded face to face with the first wafer a pump chamber, a first valve of the check-valve (mechanical closure) type

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through which said pump chamber is able to communicate selectively with one pump inlet and a second valve of the membrane type through which said pump chamber can communicate selectively with one outlet of the pump, means being provided to cause a periodic variation in the volume of said pump chamber, characterized in that said outlet communicates directly with an isolated volume of said pump chamber by means of said second valve and situated on the same side of this valve as the channel through which this valve communicates with the pump chamber in such a way that both the pressures prevailing in this pump chamber and this volume act in the direction of opening on said second valve and in that said second valve is in open communications with said first valve via said pump chamber in such a way that, during the outlet phase of the pump, this chamber communicates directly with said outlet through said second valve in the open position.

The micropump of FIGS. 1 and 2 has a base wafer 1 of, for example, glass, which is pierced by two channels 2 and 3 forming the inlet channel and the outlet channel of the pump respectively. These channels 2 and 3 communicate with connectors 4 and 5 respectively.

The connector 4 is connected to a tube 6 which in turn is connected to a reservoir 7 containing the liquid to be pumped. The reservoir is closed by a pierced cap, a movable piston isolating the working volume of the reservoir 7 from the outside. This reservoir can, for example, contain a medicament if the pump is used to inject a precise dose of this medicament into the human body. In this application the micropump can be worn on the body of the patient or implanted therein.

The outlet connector 5 may be connected to an injection needle (open jet propotioner) (not shown) joined thereto by a tube 10.

A wafer 11 of silicon or other material capable of being machined using photolithographic etching technology is bonded to the glass wafer 1. Above this silicon wafer is a glass closure wafer 12, the thickness of which is such that it can be deformed by a control element 13 which, in the application of the invention described herein, is a piezoelectric disc provided with electrodes 13a and 13b connected to an alternative voltage generator 14.

The wafers 11 and 12 together define first of all a pumping chamber 15 (see also FIG. 2) for example circular in shape, this chamber being situated below an area of the wafer 12 which can be flexed by the control element 13.

A first valve 16 of the check-valve type machined out of the silicon wafer 11 is interposed between the inlet channel 2 and the pump chamber 15. This valve is located under the pump chamber and comprises a membrane 16a substantially circular in shape and pierced in its centre by an opening 16b which is square in the embodiment shown. On the side of the channel 2, the valve 16 has an annular rib 16c which is substantially triangular in section. This rib 16c surrounds the opening 16b and is covered by a fine oxide layer 17 also obtained using photolithographic technology. This oxide layer induces an extra thickness which subjects the membrane 16a to a certain degree of bias or pretension when the top of the rib 16c bears against the glass wafer 1, the latter thus acting as seat for the valve 16.

When no electric voltage (power supply/control means) is applied to the piezoelectric disc 13, the inlet valves 16 and outlet valves 18 are in the closed position. When an electric voltage is applied, the piezoelectric disc 13 flexes, causing the wafer 12 (diaphragm) to bend towards the inside. The pressure in the pump chamber 15 therefore rises, actuating the opening of the outlet valve 18 as soon as the force acting on the membrane (diaphragm) as a result of the pressure in the chamber 15 is greater than the difference between the force created by the pretension of the valve 18, ensured by the layer of silicon oxide 17 and the force resulting from the pressure in the outlet channel 3. The fluid contained in the pump chamber is thus driven towards the outlet channel 3 by displacement of the flexible zone of the wafer 12. During this phase, the inlet valve 16 is kept closed by the pressure prevailing in the pump chamber 15. The fluid runs without encountering noteworthy resistance so that the pump chamber 15 then communicates directly with the outlet channel 3.

In contrast, when the electrical voltage is cancelled, the piezoelectric disc 13 resumes its initial shape or is flexed in the other direction so that the pressure in the pump chamber 15 falls. This causes the outlet valve 18 to close as soon as the force induced by the pressure in the pump chamber 15 is lower than the difference between the force created by the pretension of the valve and the force due to the pressure in the outlet channel 3. The inlet valve 16 opens as soon as the sum of the force due to the pressure in the pump chamber and of the force created by the pretension of the valve 16 is lower than the force due to the pressure in the inlet channel 2. There is then

aspiration of the fluid in the pump chamber 15 via the inlet channel 2 as a result of displacement of the flexible zone of the wafer 12.

Allowable Subject Matter

5. Claims 96-101 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action.

6. Claims 116-124, 127-128, and 131 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

The prior art of record does not disclose nor fairly suggest that the device comprises the proportioning control, the display, or that the operating means is accommodated on a joint printed circuit board, that the power supply is accommodated at the head region of the actuator module, a displacement means that has a screw including a servo-drive and a screw nut and sensors mounted on the screw. The prior art of record also does not disclose that the device comprises a cooling means and/or heat insulation for liquid in the reservoir, or a heating means for the liquid in the micro-diaphragm pump, the open-jet proportioner, and/or the connecting lines, means connected to a sensor for detection of a meniscus of the liquid at the beginning of a displacement length of the liquid for adjustment of an initial position for displacement of a liquid column, a proportioning control means that determines the volume being proportioned on basis of a calibration of the stroke volume that it establishes by displacing an auxiliary liquid column by the micro-diaphragm pump along with a calibration length between two sensors operatively connected with the proportion

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control means for detection of a meniscus of an auxiliary liquid column, and reservoir with a capillary balance system.

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. van Lintel (,556; ,014; ,562; ,724), Zengerle et al. (,889; ,465; and Wo 98/36832), Richter, Ross et al., Weinberg, Wojcicki et al, and Greisch et al. disclose liquid transfer devices.

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian R. Gordon whose telephone number is (703) 305-0399. The examiner can normally be reached on M-F, with 2nd and 4th F off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 703-308-4037. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9310 for regular communications and (703) 872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

brg
May 2, 2003


Jill Warden
Supervisory Patent Examiner
Technology Center 1700